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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,091	11/25/2003	Sebastiano Cavallaro	17357.01202US	4892

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EXAMINER

EMCH, GREGORY S

ART UNIT	PAPER NUMBER
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1649

MAIL DATE	DELIVERY MODE
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08/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/720,091	Applicant(s) CAVALLARO ET AL.	
	Examiner Gregory S. Emch	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-17 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) 5-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,3,5-17 and 19-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Claims 1, 3 and 19-21 have been amended and claims 2, 4 and 18 have been canceled as requested in the amendment filed on 06 June 2007. Further, the amendment to the specification has been received and entered in full. Following the amendment, claims 1, 3, 5-17 and 19-21 are pending in the instant application.

Claims 5-17 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected subject matter, there being no allowable generic or linking claim.

Claims 1, 3 and 19-21 are under examination in the instant office action.

Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicants' response and withdrawn.

Formal Matters

It is noted that although the current amendments to claims 1, 3 and 19-21 submitted 06 June 2007 properly identify portions of newly added text by underlining said text, the canceled subject matter of said claims is not correctly identified. Applicants' attention is directed to MPEP § 714 (c)(2), which states: "All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of 'currently amended,' and be submitted with markings to indicate the changes that have been made **relative to the immediate prior version of the claims**."

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The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived"

(Emphasis added).

Although the current claim listing is non-complaint (see 37 C.F.R. 1.121); in the interest of advancing prosecution, current claims 1, 3 and 19-21 will be examined.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claims 20 and 21 recite the limitation "the method of claim 1, wherein the composition..." There is insufficient antecedent basis for this limitation in the claims, since claim 1 does not recite a "composition."

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1, 3 and 19-21 under 35 U.S.C. 102(b) as being anticipated by Ellsworth et al. is maintained for reasons of record and as set forth below.

In the reply filed 06 June 2007, Applicants assert that Ellsworth et al. does not disclose the claimed invention. Applicants assert, "allegedly, the abstract by Ellsworth et al. discloses that infusion of FGF-18 reduces infarct volume and behavioral deficits, including working memory, exploratory behavior and motor activity, in a rat model for stroke caused by occlusion of the middle cerebral artery in rats. Ellsworth et al. neither teach nor suggest a method of increasing FGF-18 levels in the hippocampus of the treated subject. Ellsworth et al. discloses that infusion of FGF-18 reduces infarct volume and behavioral deficits, including working memory, exploratory behavior and motor activity, in a rat model for stroke caused by occlusion of the middle cerebral artery in rats. This model does not implicate the hippocampus."

Applicants' arguments have been fully considered and are not found persuasive. Ellsworth et al. teaches intravenous infusion of FGF-18 that reduced cerebral infarct volume and decreased deficits in reference and working memory, exploratory behavior and motor activity in rats after middle cerebral artery occlusion, thus enhancing memory, attentive cognition or learning in the individual. As stated previously, it is well known in the art that the hippocampus is involved in memory consolidation and working memory. Therefore, it is also well known to those of skill in the art IV infusion of a drug,

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in this case FGF-18, would inherently be increased in the brain (and therefore in the hippocampus) if improvement in cognition were achieved after treatment. Thus, the Ellsworth et al. abstract inherently implicates the hippocampus and thus meets the claimed limitations of "in an amount effective to increase FGF-18 levels in the subject's hippocampus." Applicants are reminded that chemical compounds and their properties are inseparable (In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA1963)), as are their processes and yields (In re Von Schickh, 362 F.2d 821, 150 USPQ 300 (CCPA 1966)). Thus, absent evidence to the contrary, the Ellsworth et al. abstract inherently implicates the hippocampus since it teaches that FGF-18 enhances memory, attentive cognition or learning (processes mediated by the hippocampus). Thus, since the reference teaches all the elements of the claims (both expressly and inherently), claims 1, 3 and 19-21 are anticipated by Ellsworth et al.

Conclusion

No claims are allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

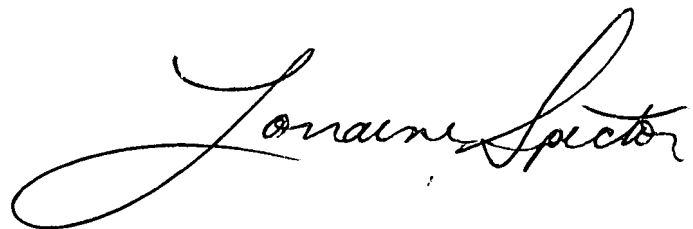
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory S. Emch/

Gregory S. Emch, Ph.D.
Patent Examiner
Art Unit 1649
13 August 2007

A handwritten signature in black ink, reading "Lorraine Spector". The signature is fluid and cursive, with a large initial "L" and a long, sweeping underline.

**LORRAINE SPECTOR
PRIMARY EXAMINER**